

1. A method for treating constipation comprising administering to a patient in need of such treatment a laxative and a peripheral opioid antagonist in amounts effective to treat the constipation.
- 5 2. The method of claim 1 wherein the patient is refractory to laxative therapy.
3. The method of claim 1 further comprising administering an opioid to the patient.
4. The method of claim 1 wherein the patient is receiving opioids chronically.
- 10 5. The method of claim 3 wherein the opioid is morphine.
6. The method of claim 1 wherein the peripheral opioid antagonist and laxative are administered in one formulation.
- 15 7. A method for treating constipation comprising administering to a patient in need of such treatment a stool softener and a peripheral opioid antagonist in amounts effective to treat the constipation.
8. The method of claim 7 wherein the patient is refractory to stool softener therapy.
- 20 9. The method of claim 7 further comprising administering an opioid to the patient.
10. The method of claim 9 wherein the opioid is administered chronically.

11. The method of claim 9 wherein the opioid is morphine.

12. The method of claim 7 wherein the peripheral opioid antagonist and stool softener are administered in one formulation.

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13. A method for treating a condition calling for treatment with a laxative comprising administering to a patient in need of such treatment a laxative and a peripheral opioid antagonist in amounts effective to treat the condition.

10 14. The method of claim 13 wherein the patient is refractory to laxative therapy.

15. The method of claim 13 further comprising administering an opioid to the patient.

16. The method of claim 15 wherein the opioid is administered chronically.

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17. The method of claim 15 wherein the opioid is morphine.

18. The method of claim 13 wherein the peripheral opioid antagonist and laxative are administered in one formulation.

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19. A method for treating a condition for treatment with a stool softener comprising administering to a patient in need of such treatment a stool softener and a peripheral opioid antagonist in amounts effective to treat the condition.

20. The method of claim 19 wherein the patient is refractory to stool softener therapy.
21. The method of claim 19 further comprising administering an opioid to the patient.
- 5 22. The method of claim 21 wherein the opioid is administered chronically.
23. The method of claim 21 wherein the opioid is morphine.
24. The method of claim 19 wherein the stool softener peripheral opioid antagonist and
10 stool softener are administered in one formulation.
25. The method of any one of claims 1 to 24 wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone.
- 15 26. The method of claim 25 wherein the peripheral opioid antagonist is methylnaltrexone.
27. The method of any one of claims 1 to 24 wherein the patient is a terminally ill patient.
28. The method of claim 27 wherein the peripheral opioid antagonist is methylnaltrexone.
- 20 29. The method of any one of claims 1 to 24 wherein the patient has an advanced medical illness.

30. The method of claim 29 wherein the peripheral opioid antagonist is methylnaltrexone.
31. The method of any one of claims 1 to 24 wherein the patient is a cancer patient.
- 5 32. The method of claim 31 wherein the peripheral opioid antagonist is methylnaltrexone.
33. The method of any one of claims 1 to 24 wherein the patient is a post-operative patient.
- 10 34. The method of claim 33 wherein the peripheral opioid antagonist is methylnaltrexone.
35. The method of any one of claims 1 to 24 wherein the patient has chronic pain.
36. The method of claim 35 wherein the peripheral opioid antagonist is methylnaltrexone.
- 15 37. The method of any one of claims 1 to 24 wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone and the patient is administered the peripheral opioid antagonist parenterally in an amount ranging from 0.001 to 1.0 mg/kg.
- 20 38. The method of claim 37 wherein the peripheral opioid antagonist is methylnaltrexone and wherein the patient is administered the methylnaltrexone parenterally in an amount ranging from 0.1 to 0.45 mg/kg.

39. The method of claim 38 wherein the amount of methylnaltrexone ranges from 0.1 to 0.3 mg/kg.

40. The method of claim 38 wherein the peripheral opioid antagonist is administered
5 parenterally.

41. The method of claim 40 wherein the peripheral opioid antagonist is administered via a route selected from the group consisting of intravenously, subcutaneously, and via a needleless injection.

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42. The method of any one of claims 1 to 24 wherein the patient is administered the peripheral opioid antagonist orally or rectally.

43. The method of claim 42 wherein the peripheral opioid antagonist is a quaternary
15 derivative of noroxymorphone and the peripheral opioid antagonist is administered in an amount ranging from 10 to 500 mg/kg.

44. The method of claim 43 wherein the peripheral opioid antagonist is administered in an enteric coated formulation.

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45. The method of claim 43 wherein the peripheral opioid antagonist is methylnaltrexone and wherein the patient is administered the methylnaltrexone orally in an amount ranging from 50 to 250 mg.

25 46. The method of claim 45 wherein the amount of methylnaltrexone ranges from 75 to 225 mg.

47. The method of any one of claims 1 to 24 wherein the patient is administered the peripheral opioid antagonist rectally.

5 48. A formulation comprising a peripheral opioid antagonist and a laxative.

49. The formulation of claim 48 wherein the opioid antagonist and the laxative are formulated as a suppository.

10 50. The formulation of claim 49, wherein the peripheral opioid antagonist forms a core of the suppository.

51. The formulation of claim 49, wherein the peripheral opioid antagonist is distributed throughout the suppository.

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52. The formulation of claim 49, wherein the peripheral opioid antagonist is coated with a pharmaceutically acceptable carrier.

20 53. The formulation of claim 49, wherein the peripheral opioid antagonist comprises particles.

54. The formulation of claim 51, wherein the particles are coated with a pharmaceutically acceptable carrier.

55. The formulation of claim 48, wherein the formulation is an oral formulation.

56. The formulation of claim 55, wherein the peripheral opioid antagonist forms a core of the oral preparation.

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57. The formulation of claim 55, wherein the peripheral opioid antagonist is distributed throughout the oral formulation.

58. The formulation of claim 55, wherein at least a portion of the peripheral opioid
10 antagonist is coated with a pharmaceutically acceptable carrier.

59. The formulation of claim 58, wherein the pharmaceutically acceptable carrier is an enteric coating.

15 60. The formulation of claim 59, wherein the laxative is not enterically coated.

61. The formulation of claim 55, wherein at least a portion of the laxative is coated with a pharmaceutically acceptable carrier.

20 62. The formulation of claim 61, wherein the pharmaceutically acceptable carrier is an enteric coating.

63. The formulation of claim 62, wherein the peripheral opioid antagonist is not enterically coated.

64. The formulation of claim 55, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist in the stomach, the small intestine, and the colon.

5 65. The formulation of claim 55, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist only in the small intestine and colon.

66. The formulation of claim 55, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist only in the small intestine.

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67. The formulation of claim 55, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist only in the colon.

15 68. The formulation of claim 55, wherein the formulation is constructed and arranged to release immediately substantially all of the peripheral opioid antagonist in the stomach.

69. The formulation of claim 48, wherein the peripheral opioid antagonist is in or coated with a sustained release material.

20 70. The formulation of claim 48, wherein the peripheral opioid antagonist is in an enteric coated sustained release material.

71. The formulation of claim 69, wherein the laxative is not in a sustained release material.

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72. The formulation of claim 48, wherein the laxative is in or coated with a sustained release material.

5 73. The formulation of claim 72, wherein the sustained release material is a matrix or membrane.

74. The formulation of claim 48, wherein the laxative is an enteric coated sustained release material.

10 75. The formulation of claim 72, wherein the peripheral opioid antagonist is not in a sustained release material.

76. The formulation of any one of claims 48 to 75, wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone.

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77. The formulation of claim 76 wherein the peripheral opioid antagonist is methylnaltrexone.

20 78. The formulation of claim 77, wherein the methylnaltrexone is present in a range from 50 to 250 mg.

79. The formulation of claim 77, wherein the formulation further comprises an opioid.

80. A formulation comprising a peripheral opioid antagonist and a stool softener.

81. The formulation of claim 80, wherein the opioid antagonist and the stool softener are formulated as a suppository.
- 5 82. The formulation of claim 80, wherein the peripheral opioid antagonist forms a core of the suppository.
83. The formulation of claim 80, wherein the peripheral opioid antagonist is distributed throughout the suppository.
- 10 84. The formulation of claim 80, wherein the peripheral opioid antagonist is coated with a pharmaceutically acceptable carrier.
- 15 85. The formulation of claim 80, wherein the peripheral opioid antagonist comprises particles.
86. The formulation of claim 85, wherein the particles are coated with a pharmaceutically acceptable carrier.
- 20 87. The formulation of claim 80, wherein the formulation is an oral formulation.
88. The formulation of claim 87, wherein the formulation is a liquid, semi-solid or solid.

89. The formulation of claim 87, wherein the peripheral opioid antagonist forms a core of the oral preparation.

5 90. The formulation of claim 87, wherein the peripheral opioid antagonist is distributed throughout the oral formulation.

91. The formulation of claim 87, wherein at least a portion of the peripheral opioid antagonist is coated with a pharmaceutically acceptable carrier.

10 92. The formulation of claim 91, wherein the pharmaceutically acceptable carrier is an enteric coating.

93. The formulation of claim 91, wherein the pharmaceutically acceptable carrier is a sustained release coating.

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94. The formulation of claim 93, wherein the stool softener is not enterically coated.

95. The formulation of claim 87, wherein at least a portion of the stool softener is coated with a pharmaceutically acceptable carrier.

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96. The formulation of claim 95, wherein the pharmaceutically acceptable carrier is an enteric coating.

25 97. The formulation of claim 95, wherein the pharmaceutically acceptable carrier is a sustained release coating.

98. The formulation of claim 96, wherein the peripheral opioid antagonist is not enterically coated.

5 99. The formulation of claim 87, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist in the stomach, the small intestine, and the colon.

100. The formulation of claim 87, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist in the small intestine and colon.

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101. The formulation of claim 87, wherein the formulation is constructed and arranged to release the peripheral opioid antagonist in the small intestine.

102. The formulation of claim 87, wherein the formulation is constructed and arranged to
15 release the peripheral opioid antagonist only in the colon.

103. The formulation of claim 87, wherein the formulation is constructed and arranged to release immediately substantially all of the peripheral opioid antagonist in the stomach.

20 104. The formulation of claim 80, wherein the peripheral opioid antagonist is in a sustained release material.

105. The formulation of claim 104, wherein the stool softener is not in a sustained release material.

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106. The formulation of claim 80, wherein the stool softener is in a sustained release material.

107. The formulation of claim 106, wherein the peripheral opioid antagonist is not in a
5 sustained release material.

108. The formulation of any one of claims 80 to 107, wherein the peripheral opioid antagonist is a quaternary derivative of noroxymorphone.

109. The formulation of claim 108, wherein the peripheral opioid antagonist is
10 methylnaltrexone.

110. The formulation of claim 109, wherein the methylnaltrexone is present in a range
from 50 to 250 mg.

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111. The formulation of claim 110, wherein the formulation further comprises an opioid.

112. A kit comprising:

a package containing a formulation of a peripheral opioid antagonist and a laxative
20 and/or a stool softener.

113. The kit of claim 112, wherein the formulation is the formulation of any one of claims
48 to 111.

114. The kit of claim 112, wherein the peripheral opioid antagonist is in a first container and the laxative and/or stool softener are in a container different from the first container.